ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
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IMPORTANT DRUG WARNING

Dear Healthcare Professional:

Abbott would like to inform you of new warnings regarding use with anakinra, hypersensitivity reactions, and hematologic events added to the prescribing information for HUMIRA® (adalimumab), a biological therapeutic product indicated for the treatment of rheumatoid arthritis. Enclosed please find the updated prescribing information as well as the patient information sheet.

The United States Food and Drug Administration ("FDA") has received information regarding serious infections observed with the use of anakinra and another TNF-blocking agent, and has requested that all manufacturers of TNF-blocking agents add the following new information to the Warnings Section of the prescribing information:

Use with Anakinra

Serious infections were seen in clinical studies with concurrent use of anakinra (an interleukin-1 antagonist) and another TNF-blocking agent, with no added benefit. Because of the nature of the adverse events seen with this combination therapy, similar toxicities may also result from combination of anakinra and other TNF blocking agents. Therefore, the combination of HUMIRA and anakinra is not recommended (see PRECAUTIONS, Drug Interactions).

In addition, Abbott has received rare post-marketing reports of anaphylaxis. As a result, Abbott has included the following new information in the Warnings Section of the prescribing information:

Hypersensitivity Reactions

In postmarketing experience, anaphylaxis has been reported rarely following HUMIRA administration. If an anaphylactic or other serious allergic reaction occurs, administration of HUMIRA should be discontinued immediately and appropriate therapy instituted. In clinical trials of HUMIRA, allergic reactions overall (e.g., allergic rash, anaphylactoid reaction, fixed drug reaction, non-specified drug reaction, urticaria) have been observed in approximately 1% of patients.

Finally, Abbott has received infrequent reports of hematologic events, including medically significant cytopenia with the use of HUMIRA, and the FDA has received rare reports of pancytopenia, including aplastic anemia, with TNF-blocking agents. As a result, Abbott has included the following new information in the Warnings Section of the prescribing information:

Hematologic Events

Rare reports of pancytopenia including aplastic anemia have been reported with TNF-blocking agents. Adverse events of the hematologic system, including medically significant cytopenia (e.g. thrombocytopenia, leukopenia) have been infrequently reported with HUMIRA (see ADVERSE REACTIONS, Other Adverse Reactions). The causal relationship of these reports to HUMIRA remains unclear. All patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g. persistent fever, bruising, bleeding, pallor) while on HUMIRA. Discontinuation of HUMIRA therapy should be considered in patients with confirmed significant hematologic abnormalities.

Abbott is committed to ensuring that HUMIRA is used safely and effectively and to providing you with the most current product information for HUMIRA. You can assist us with monitoring the safety of HUMIRA by reporting adverse events to Abbott at 1-800-633-9110. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (l-800-FDA-1088), facsimile (l-800-FDA-0178), the MedWatch website at www.fda.gov/medwatch, or mailed to MedWatch, HF-5600 Fishers Lane, Rockville, MD 20852-9787. Both healthcare professionals and consumers should use Form 3500 for reporting adverse events.

Should you have any questions or require further information regarding the use of HUMIRA, please contact Abbott's Medical Information Department at 1-800-633-9110.

Sincerely,

George Spencer-Green, MD, MS
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Abbott Immunology

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